ROPES & GRAY

DLA PIPER

July 30, 2020

VIA E-MAIL
Honorable Mary Kay Vyskocil
Daniel Patrick Moynihan U.S. Courthouse
500 Pearl Street
New York, NY 10007-1312

Re: ***Pfizer Inc. v. U.S. Department of Health and Human Services et al.***
Case No.: 20-cv-04920-MKV

Dear Judge Vyskocil:

Pfizer Inc. ("Pfizer") seeks to file a motion for judgment under Federal Rule of Civil Procedure 57 and respectfully requests an initial conference and pre-motion conference with the Court pursuant to the Court's Rule of Civil Practice 4(A)(i).

1. *Introduction:* On June 26, 2020, Pfizer filed this action seeking a declaratory judgment that the Anti-Kickback Statute ("AKS") and Benefit Inducement Statute ("BIS") do not prohibit Pfizer from helping financially needy Medicare patients meet Medicare Part D copay requirements for tafamidis,[1] the only pharmacological treatment approved by the U.S. Food and Drug Administration ("FDA") for a rare and fatal condition called Transthyretin Amyloid Cardiomyopathy ("ATTR-CM"). Without this Court's intervention, Pfizer is unable to provide this financial assistance because of the significant risk of a criminal or other government enforcement action arising from erroneous legal restrictions imposed by defendants, including the U.S. Department of Health and Human Services, Office of Inspector General ("HHS-OIG"). As a result, Medicare beneficiaries who are unable to afford copay obligations under Medicare Part D will continue to be denied access to their Medicare benefits and these life-changing medical breakthroughs.

Pfizer's complaint seeks expedited resolution of this issue pursuant to Rule 57 because of the urgent patient need to access this treatment. See Fed. R. Civ. P. 57 (permitting the Court to "order a speedy hearing of a declaratory-judgment action").[2] Pfizer seeks to achieve an expeditious resolution by filing a motion for judgment under Rule 57

[1] Known by brand names VYNDAQEL® (tafamidis meglumine) or VYNDAMAX™ (tafamidis).

[2] This Court has granted expedited consideration where, as here, there is a "pressing need . . . for definitive resolution," and "[a]ny unnecessary delay likely would be seriously prejudicial." *Chevron Corp. v. Donziger*, 800 F. Supp. 2d 484, 491 (S.D.N.Y. 2011); *see also Beacon Constr. Co., Inc., v. Matco Elec. Co., Inc.*, 521 F.2d 392, 397 (2d Cir. 1975) (The Declaratory Judgment Act is designed to "afford a speedy and inexpensive method of adjudicating legal disputes . . . to settle legal rights and remove uncertainty and insecurity from legal relationships without awaiting a violation of the rights or a disturbance of the relationships.") (quotation omitted); 10B Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2751 (4th ed. 2019).

at the outset of the case because this case presents a pure legal question based on Pfizer's proposed patient assistance programs. Pfizer further respectfully requests this Court establish a briefing schedule whereby the Government would file a consolidated brief stating any opposition to Pfizer's motion on procedural and substantive grounds.

2. *Grounds for the Motion:* Pfizer's motion under Rule 57 will demonstrate that, contrary to HHS-OIG's position, Pfizer's proposed financial assistance programs are not prohibited by either the AKS or the BIS. The programs are not intended to, and would not, corruptly "influence" or "induce" medical decisions, but would serve only to support access for patients properly prescribed tafamidis. Additionally, providing copay assistance would not constitute prohibited "remuneration" under those federal statutes because such assistance would not be offered as a *quid pro quo* in exchange for conduct by the recipient. Pfizer's program is further expressly exempted by statute and regulation because it poses a low risk of harm to federal healthcare programs.

Through its guidance, advisory opinions, and enforcement decisions, HHS-OIG has incorrectly construed the AKS and BIS to categorically ban pharmaceutical manufacturers—but not others—from providing copay assistance to Medicare patients. HHS-OIG's expansive interpretation of AKS and BIS exceeds the statutes, which target fraud and bribery in medical decision-making, not programs that allow access to appropriate medical treatment.

By effectively limiting access to tafamidis based on a beneficiary's economic status, HHS-OIG's legal position also raises equal protection concerns under the U.S. Constitution. In the absence of Pfizer's proposed patient assistance, two Medicare beneficiaries—each with the same medically certain diagnosis, and each of whom has been prescribed tafamidis—would face substantial disparities in access to crucial medical treatments and to federal insurance benefits for which they have paid based on nothing other than their ability to afford Medicare Part D copays. Contrary to the position adopted by HHS-OIG, ensuring equitable access to Pfizer's breakthrough medicine for financially needy patients does not violate the AKS and BIS.

Pfizer also seeks a declaration that it is free to fund and communicate with independent charities that provide financial assistance to Medicare patients, notwithstanding HHS OIG's contrary position. Through its advisory opinions and other actions, OIG has interpreted the AKS and BIS in a manner that imposes strict restrictions on pharmaceutical manufacturers' constitutionally protected speech and charitable activities. Beyond having no basis in the AKS or BIS, such restrictions on communication with and donations to independent charities would raise significant concerns under the First Amendment.

Finally, Pfizer seeks a declaration that HHS-OIG violated the Administrative Procedure Act, 5 U.S.C § 706(2)(A) & (B), by precluding Pfizer from implementing its proposed programs through a series of action that are "not in accordance with law" or "contrary to constitutional right," including (1) the agency's 2005 and 2014 guidance establishing its position that the AKS and BIS categorically prohibits pharmaceutical manufacturers from providing copay assistance directly to Medicare patients and setting

forth the agency's restrictions on donations to and communications with independent charities; and (2) its enforcement history; which understanding has been confirmed by (3) OIG's recent refusal to grant Pfizer a favorable advisory opinion for its proposed programs.

3. *Proposed Procedure*: Pfizer has conferred with the government, which indicated it will seek to delay its response to the complaint until mid-September 2020 to enable HHS OIG to issue a written opinion on Pfizer's August 26, 2019 advisory opinion request.

Pfizer respectfully disagrees that resolution of this case depends on any further action by HHS OIG. Pfizer seeks a declaration that is now ripe for review: it intends to implement its financial assistance program to enable ATTR-CM patients to access tafamidis, but is presently prevented from doing so by the imminent risk of enforcement action if it proceeds. Pfizer's request for an advisory opinion has been pending with HHS OIG for more than one year, notwithstanding Congress' directive that any advisory opinion be issued within 60 days of submission—a deadline that has long passed. 42 U.S.C § 1320a–7d(b)(5)(B)(i). Many ATTR-CM patients, meanwhile, have been unable to afford treatment.

Although there was no requirement that Pfizer invoke OIG's advisory opinion process, in an attempt to cooperate with OIG and in hopes of avoiding contentious litigation, Pfizer filed an advisory opinion request to explain to OIG that Pfizer's proposed program would not fall within the ambit of the AKS or BIS. On May 26, 2020, HHS-OIG definitively told Pfizer that it had decided to deny the request for a positive advisory opinion. That decision confirms that no further avenue for relief is possible from the agency and Pfizer cannot implement its proposed patient assistance programs without imminent risk of enforcement action. In this suit, Pfizer seeks a legal determination that its proposed programs do not violate the BIS and AKS. Pfizer does not seek review of HHS-OIG's discretionary application of its prosecutorial authority, which would be the subject of any written advisory opinion. To the extent the agency seeks to explain its view of the relevant statutes, its responsive brief will accord it that opportunity. Accordingly, there is no need to wait for HHS-OIG to take any further action.

In light of the compelling reasons to expedite this matter, Pfizer proposes that this case be resolved by cross-motion practice, as has been the case in other, analogous situations. For instance, in *Allergan, Inc. v. U.S.*, a case challenging FDA's regulations related to off-label promotion, the court and parties agreed to an expedited schedule that converted a motion for preliminary injunction into one for a permanent injunction and to address that motion and the merits simultaneously through cross-dispositive motions. *See* No. 1:09-cv-01879-JDB (D.D.C., filed Oct. 1, 2009). Pfizer proposes that it would file a dispositive motion for declaratory judgment by August 15, 2020, and that the government would then file it dispositive cross-motions on both procedural and substantive grounds, to be followed by reply briefs, according to an expedited briefing schedule.

Sincerely,

/s/Ilana H. Eisenstein

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Attorneys for Plaintiff Pfizer Inc.

CERTIFICATE OF SERVICE

I hereby certify that on the 30th day of July 2020, I caused to be served a true and correct copy of the foregoing Letter Motion via ECF and electronic mail on all counsel of record in this action.

/s/ Ilana H. Eisenstein

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Ilana H. Eisenstein